



## **Drug Enforcement Administration**

**[Docket No. DEA-1176]**

### **Bulk Manufacturer of Controlled Substances Application: SpecGx LLC**

**AGENCY:** Drug Enforcement Administration, Justice.

**ACTION:** Notice of application.

**SUMMARY:** SpecGx LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

**DATES:** Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <https://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on <https://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 1301.33(a), this is notice that on February 14, 2023, SpecGx LLC, 3600 North 2<sup>nd</sup> Street, Saint Louis, Missouri 63147-

3457, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

<b>Controlled Substance</b>	<b>Drug Code</b>	<b>Schedule</b>
Gamma Hydroxybutyric Acid	2010	I
Tetrahydrocannabinols	7370	I
Psilocybin	7437	I
Codeine-N-oxide	9053	I
Noroxymorphone	9145	I
Difenoxin	9168	I
Morphine-N-oxide	9307	I
Normorphine	9313	I
Alphamethadol	9605	I
Betamethadol	9609	I
Norlevorphanol	9634	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I
Butyryl Fentanyl	9822	I
Fentanyl related-compounds as defined in 21 CFR 1308.11(h)	9850	I
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Nabilone	7379	II
ANPP (4-Anilino-N-phenethyl-4-piperidine)	8333	II
Phenylacetone	8501	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Hydrocodone	9193	II
Levorphanol	9220	II
Isomethadone	9226	II
Meperidine	9230	II
Meperidine intermediate-A	9232	II
Meperidine intermediate-B	9233	II
Meperidine intermediate-C	9234	II
Methadone	9250	II
Methadone intermediate	9254	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Morphine	9300	II
Oripavine	9330	II

Thebaine	9333	II
Opium tincture	9630	II
Opium, powdered	9639	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Tapentadol	9780	II
Fentanyl	9801	II
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Pentobarbital	2270	II
4-Anilino-N-Phenethyl-4-Piperidine (ANPP)	8333	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to bulk manufacture the listed controlled substances for sale to its customers as Active Pharmaceutical Ingredients (APIs) and Analytical Research Standards (ARS) for formulation and analytical development purposes. In reference to drug codes 7360 (Marihuana), and 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

**Matthew Strait,**

*Deputy Assistant Administrator.*

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